

REMARKS/ARGUMENTS

The above-identified application has been reviewed in light of the Office Action dated February 7, 2007. By the present amendment, the Applicant has amended claim 15 and added new claim 30. It is respectfully submitted that this amendment adds no new matter and is fully supported by the specification. In light of the aforementioned amendment, and the remarks and arguments that follow, reconsideration and allowance of the present application are earnestly solicited.

In the Office Action, claims 15-20 and 27-29 were rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement, and under 35 U.S.C. § 112, second paragraph, as being indefinite. It was asserted that the recitation of “a plurality of filaments disposed within an interior of the inflatable bladder” in independent claim 15 was not sufficiently described in the specification. In the interests of furthering prosecution and without acquiescing to the rejections of the Office Action, independent claim 15 has been amended, without prejudice, to remove the rejected claim language. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, first and second paragraphs, is respectfully requested.

Claims 15-20 and 27-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,417,745 to Sheldon (hereinafter “Sheldon”) in view of U.S. Patent No. 4,796,629 to Grayzel (hereinafter “Grayzel”). It was asserted in the Office Action that Fig. 3 of Sheldon discloses a cannula, a shaft, and an inflatable bladder that may exhibit an eccentric or wedge shape upon inflation. It was further asserted that the inflatable bladder disclosed in Sheldon is inherently capable of separating adjacent layers of tissue since the bladder is made of a very strong inelastic material and is inflated with a substantially non-compressible material. The Office Action acknowledged that Sheldon fails to disclose a plurality of filaments within an

Sheldon, therefore, discloses an inflatable member 50 that is mounted externally of and fixed to the distal end of cannula or housing 23, and not “at least partially disposed within the

passage prior to inflation and axially movable therethrough,” as recited in amended independent claim 15. Moreover, disposition of the inflatable member 50 “at least partially” within the cannula or housing 23, as recited in independent claim 15, would obscure the clinician or operator’s view of the target site through window 18a, thereby frustrating the purpose of the device. The addition of the filaments disclosed in Grayzel fails to cure these deficiencies in Sheldon.

Accordingly, it is respectfully submitted that Sheldon in view of Grayzel fails to suggest each and every limitation recited in amended independent claim 15, and therefore, that claim 15 is in condition for allowance. As claims 16-20 and 27-29 depend directly or indirectly from claim 15, it is respectfully submitted that these claims are also in condition for allowance.

Claims 15-20 and 27-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,875,595 to Froning in view of Grayzel. The Office Action asserted that Froning discloses a cannula, a shaft, and an inflatable bladder that may exhibit an eccentric shape upon inflation, wherein the bladder may be moved axially with respect to the cannula, and is inherently capable of separating adjacent layers of tissue since the bladder is made of a material that is sufficiently strong to hold fluid under pressure, and is filled with a substantially non-compressible material. The Office Action acknowledged that Froning fails to disclose a plurality of filaments within an interior of the inflatable bladder, and again relied on Grayzel for the disclosure thereof. It is respectfully submitted, however, that Froning in view of Grayzel fails to suggest each and every limitation of the apparatus recited in amended independent claim 15.

As amended, independent claim 15 recites an apparatus comprising, *inter alia*, a cannula defining a passage, a shaft, and an inflatable bladder disposed at the distal end of the shaft wherein “at least a portion of the inflatable bladder being disposed externally of the passage and

adjacent tissue following the inflation thereof such that subsequent axial movement of the shaft defines a working space between the adjacent layers of tissue."

Froning discloses an instrument that includes a tube or cannula 31 through which a stem or shaft 47 is inserted, as seen below in FIG. 4, to replace the nucleus of a vertebral disc with an inflatable prosthetic member 46 (Column 2, lines 25-26).

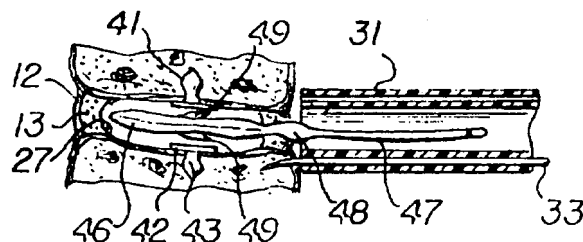
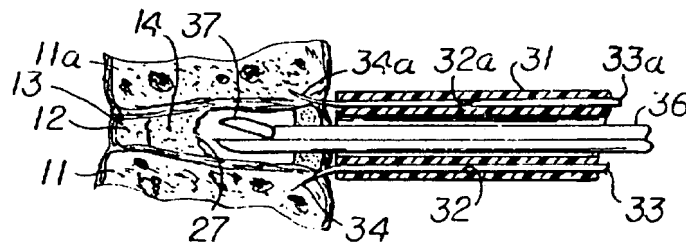


Fig. 4

Froning discloses that prosthesis 46 has the properties of a normal disc, which is substantially resilient and flexible in character, functioning to permit the articulation of vertebrae adjacent thereto (Column 3, lines 19-24). In order to perform this function, prosthesis 46 must be substantially, if not completely, immovable following inflation between the vertebrae. Froning, therefore, fails to suggest an inflatable bladder disposed at the distal end of a shaft that is "axially movable therethrough, at least a portion of the inflatable bladder being disposed externally of the passage and adjacent tissue following the inflation thereof such that subsequent axial movement of the shaft defines a working space between the adjacent layers of tissue" as recited in amended independent claim 15. In addition, Froning discloses that forceps 36, and not the inflatable prosthesis 46, are used to remove the nucleus of the disc 12 to be replaced, and thereby create a void or workspace 27 into which the prosthesis 46 is subsequently installed (Column 2, lines 53-58 and FIG. 2 below).

**Fig. 2**

Accordingly, Froning fails to suggest an apparatus including an inflatable bladder disposed at the distal end of a shaft that is "axially movable therethrough, at least a portion of the inflatable bladder being disposed externally of the passage and adjacent tissue following the inflation thereof such that subsequent axial movement of the shaft defines a working space between the adjacent layers of tissue" as recited in amended independent claim 15. The addition of the filaments disclosed in Grayzel fails to cure these deficiencies in Froning.

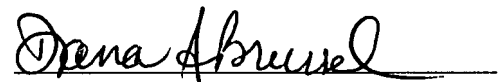
Accordingly, it is respectfully submitted that Froning in view of Grayzel fails to suggest each and every limitation recited in amended independent claim 15, and therefore, that claim 15 is in condition for allowance. As claims 16-20 and 27-29 depend directly or indirectly from claim 15, it is respectfully submitted that these claims are also in condition for allowance.

By the present amendment, the Applicant has added new claim 30, which depends from independent claim 15. Since claim 15 is allowable over the art of record, it is respectfully submitted that new claim 30 is also allowable.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 15-20 and 27-30, are in condition for allowance. Should the Examiner believe that an interview may facilitate the resolution of any outstanding issues, the Examiner is respectfully requested to telephone the Applicant's attorney. Early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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